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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,071	09/13/2005	Pascal Bernard	0579-1082	5118
<div>466 7590 01/14/2009</div> <div>YOUNG & THOMPSON</div> <div>209 Madison Street</div> <div>Suite 500</div> <div>ALEXANDRIA, VA 22314</div>				
EXAMINER				
MARCETICH, ADAM M				
ART UNIT		PAPER NUMBER		
3761				
MAIL DATE		DELIVERY MODE		
01/14/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/520,071

Applicant(s)

BERNARD ET AL.

Examiner

Adam Marcetich

Art Unit

3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 October 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 05 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 23 October 2008 has been entered.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). A certified copy of parent Application No. France 0208467, filed on 05 July 2002 has been received.

Claim Rejections - 35 USC § 103

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

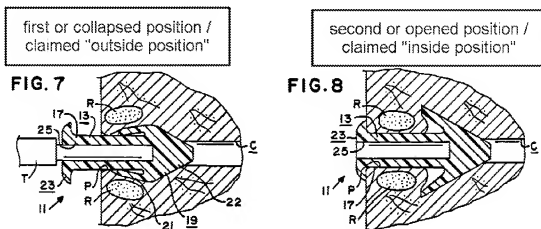
6. Claims 1-7, 9-16 and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US 5830171) in view of Roschak, Ed et al. (US 20020087153).

7. Regarding claims 1 and 20, Wallace discloses a punctal occluder (column 2, lines 29-37) adaptable for use as a meatal occluder of a human eye, comprising:

a substantially cylindrical body (column 3, lines 50-54 and Figs. 1-3, shank 13) characterized in that it further comprises:

at least one fin adapted to take up an outside position outside the lachrymal meatus wherein the fin is substantially folded into the cylindrical body (column 3, lines 55-64, especially lines 60-61 and Fig. 7, wing portion 21 having a first collapsed position, see annotated figure below. Regarding the limitation of being outside the lachrymal meatus, it is the Examiner's position that wing portion 21 of Wallace may be placed within a different physiological lumen, or held in its folded position manually or by deployment means.); and

an inside position into the lachrymal meatus wherein the fin projects from the cylindrical body (column 3, lines 64-67, especially lines 64-65 and Fig. 8, wing portion 21 having second expanded position, see annotated figure below).

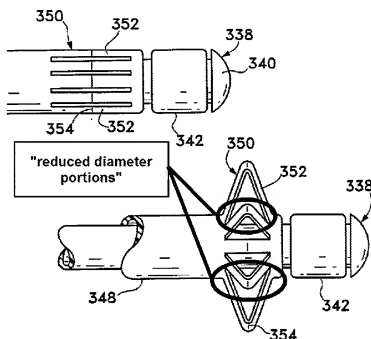


Annotated Figs. 7, 8 of Wallace

Examiner notes that Wallace uses the same material, silicone (column 5, lines 8-13) as disclosed in the immediate specification (p. 8, lines 1-5, especially line 2), therefore the material used by Wallace is fully capable of being heat-deformable as claimed [claim 1].

Wallace discloses the invention substantially as claimed, see above. However, Wallace lacks a reduced diameter portion as claimed [claims 1 and 20]. Roschak discloses a pulmonary implant (§ [0016] "... devices and methods for altering gaseous flow in a diseased lung. . ."), made of a heat-deformable material (§ [0028], "... shape memory alloys, shape memory polymers. . .") further comprising a reduced diameter portion (§ [0079], Figs. 3L, 3M, shoulder 350 comprising hinged members 352, "... each of which is adapted to expand in diameter from the expandable member 348 . . . hinged

members 352 to assume an expanded or reduced profile." Examiner interprets hinged members 352 folded against the body of elongate body 348 as forming reduced diameter portions, since recesses are apparent when the hinged members 352 are folded into a deployed state (see annotated Figs. 3L, 3M below).



Annotated Figs. 3L and 3M of Roschak, Ed et al. (US 20020087153).

Roschak provides the advantage of providing a streamlined shape when inserting an implant. This is valuable for placing an expanding stent into a physiological lumen, for easily inserting the stent and preserving structures within the lumen. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wallace as discussed with the reduced diameter portion as taught by Roschak in order to effectively deploy an expanding stent within a lumen.

8. Regarding claims 2 and 3, Wallace discloses a meatal occluder characterized in that it is made from silicone (column 5, lines 8-13). Examiner notes that silicone is a heat-expandable material, since it is capable of expanding when heated. In other words, the language "heat-expandable" is being interpreted to include materials that expand when heated, such as silicone. Additionally, Applicant discloses silicone as a suitable heat-expandable material for forming the implant (immediate specification, p. 7-8, lines 35-5, especially line 2 and lines 11-15, especially line 13, "silicones"). Therefore, Examiner interprets the silicone material of Wallace as anticipating the claimed heat-expandable material.

In the alternative, Roschak also discloses:

a silicone material (§ [0081], "...elongated member 360 . . . comprised of, for example: silicone. . ."); and

a heat-expandable material (§ [0028], "... shape memory alloys, shape memory polymers. . .").

Roschak provides the advantage of a material capable of being activated by the application of heat, useful in selectively deploying anchoring portions. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the invention of Wallace as discussed with the silicone or heat-expandable material as taught by Roschak in order to deploy anchoring portions.

9. Regarding claim 4, Wallace discloses the invention as substantially claimed. See above. Wallace discloses an implant comprising silicone as discussed above. The specification of the immediate application discloses silicone as a polymer capable of

having a vitreous transition temperature from -10°C to 30° (page 8, lines 11-15).

Therefore, the property of vitreous transition temperature is an intrinsic property of the materials used, and the device of Wallace is capable of having a vitreous transition temperature from -10°C to 30°C.

10. Regarding claim 5, Wallace discloses a meatal occluder characterized in that said fin pivots between said folded position and said extended position about an axis perpendicular to a longitudinal plane of said meatal occluder (column 4, lines 35-42 and Figs. 7 and 9, wing portion 21 pivoting about axis perpendicular to longitudinal plane of shank 13).

11. Regarding claim 6, Wallace depicts a meatal occluder characterized in that said fin when in said folded position extends in a direction substantially parallel to the longitudinal direction of the cylindrical body (Fig. 7, wing portion 21 extending substantially parallel to shank 13).

12. Regarding claim 7, Wallace depicts a meatal occluder characterized in that said fin is situated in the vicinity of one end of said cylindrical body, a free end of said fin, when in the folded position, extending in the direction of the opposite end of said cylindrical body (Fig. 9, end of wing portion 21 having folded position extending in direction opposite of shank 13).

13. Regarding claim 9, Wallace discloses a meatal occluder characterized in that said fin is situated in the vicinity of a tapered end of said cylindrical body, the opposite end of said cylindrical body comprising a flange (column 4, lines 22-24 and 43-49; Figs. 2 and 3, flange 23 near nose portion 22).

14. Regarding claim 10, Wallace discloses a meatal occluder characterized in that it comprises a plurality of fins regularly distributed on the cylindrical body of said occluder (column 4, lines 22-24, "wing portion 21 may be formed by a plurality of individual wing elements").

15. Regarding claim 11, Wallace discloses a punctal occluder (column 2, lines 29-37), adaptable for use as a meatal occluder of a human eye, comprising:

a substantially cylindrical body having a longitudinal axis (see discussion of claim 1 above);

at least one fin comprising a heat-deformable material (see discussion of claim 1 above, especially section on heat-expandable material); and

the at least one fin having a first position in which the at least one fin extends from the cylindrical body substantially parallel to the longitudinal axis (Fig. 7, wing portion 21 having a first collapsed position, extending substantially parallel to longitudinal axis).

Wallace discloses the invention as substantially claimed, see above. However, Wallace lacks a fin positioned to extend as claimed [claim 11].

Roschak discloses a pulmonary implant comprising:

a fin (§ [0079], Figs. 3L, 3M, shoulder 350 comprising hinged members 352); and
made of a heat-deformable material (§ [0028], ". . . shape memory alloys, shape memory polymers. . .")

capable of moving from a first position of being arranged substantially parallel to the longitudinal axis (Fig. 3L, hinged members 350 folded parallel to longitudinal axis of expandable member 348);

to a second position in which the at least one fin extends outward from the longitudinal axis (Fig. 3M, hinged members 350 extending outwards from longitudinal axis of expandable member 348). Regarding rationale and motivation, see discussion of claims 1 and 20 above.

16. Regarding claims 12, 13, 14, 15, 16, 18 and 19, see discussion of claims 2, 3, 4, 5, 7, 9 and 10 above, respectively.

17. Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace (US Patent 5,830,171) in view of Roschak, Ed et al. (US 20020087153), further in view of Fouere (US Patent 6,254,562).

18. Regarding claims 8 and 17, Wallace in view of Roschak discloses the invention as substantially claimed. See above. However, Wallace in view of Roschak lacks a fin pivoting between a folded position and an extended position about an axis parallel to the longitudinal direction of a cylindrical body as claimed [claims 8 and 17]. Fouere discloses a meatal occluder having fins pivoting between a folded position and an extended position about an axis parallel to the longitudinal direction of the cylindrical body (column 2, lines 50-56; Fig. 2, gripping means 12). Fouere provides the advantage of preventing involuntary expulsion of a meatal occluder (column 1, lines 59-64).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the invention of Wallace in view of Roschak as discussed with the pivoting fins as taught by Fouere in order to prevent involuntary expulsion of a meatal occluder.

Response to Arguments

19. Applicant's arguments, see p. 8-12 filed 23 October 2008 with respect to the rejection(s) of claim(s) 1-19 under 35 USC § 102 and 103 over Wallace, Fouere and Zhou have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of under 35 USC § 103 over Wallace, Roschak and Zhou.

20. Applicant asserts that Wallace lacks a reduced diameter portion of the cylindrical body, as appears in claim 1 and is exemplified by Fig. 2B of the present application. Examiner notes that Roschak teaches a reduced diameter of a cylindrical body applied to retaining a cylindrical body within a physiological lumen, as discussed in the new grounds of rejection.

21. Applicant contends that Zhou lacks an exterior of a fin arranged so as to preserve the cylindrical shape of the cylindrical body, as appears in claim 11 and Fig. 2B of the present application. Examiner notes that Roschak teaches this limitation as discussed above.

22. Applicant asserts that Fouere fails to remedy shortcomings of Wallace and Zhou. Examiner notes that Fouere is relied upon for the limitation of pivoting pins, while

Roschak teaches a reduced diameter and fins arranged so as to preserve the cylindrical shape of a cylindrical body.

23. If any amendments to the claims are desired for overcoming rejections of record, Examiner recommends phrasing them in positive language. While negative limitations are legitimate and do not preclude patentability, positive recitations are generally more effective. There is nothing inherently ambiguous or uncertain about a negative limitation, as long as it is properly supported by the specification. See MPEP 2173.05(i), Negative Limitations. However, adding language to positively claim structures and functions is generally more helpful in clearly defining the invention as compared to negative limitations, since the presence of a structure or function is more easily seen, depicted or discerned than its absence or omission.

Conclusion

24. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- ◆ Flomenblit; Josef et al. US 5876434
- ◆ Tillay; Michael J. US 4666445
- ◆ Wilson, Peter M. et al. US 20030070682

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-

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2590. The examiner can normally be reached on 8:00am to 4:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Adam Marcetich/
Examiner, Art Unit 3761

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
13 January 2008